K062320

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9 510(K) SUMMARY

Submitted by:

Perry W. Guinn
VP Regulatory Affairs and Quality Assurance
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 497-3355
August 8, 2006

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Device:	
Trade Name:	SURGISIS® Peyronie's Repair Graft
Common/Usual Name:	Surgical Mesh
Proposed Classification Name:	Surgical Mesh 21 CFR §878.3300 (79FTM) Class II

Intended Use:
The SURGISIS® Peyronie's Repair Graft is intended for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to the repair of tunica albuginea defects, and reinforcement in the repair of Peyronie's disease. This device is supplied sterile and is intended for one-time use only.

Predicate Devices:
The SURGISIS® Peyronie's Repair Graft is similar in terms of substantial equivalence to the following predicate devices: SURGISIS® Sling (K992159) and SURGI*S/S*® Mesh (K980431) devices, both manufactured by Cook Biotech Incorporated, and AMS Collagen Dermal Matrix (K050445) manufactured by American Medical Systems.

Device Description:
The SURGISIS® Peyronie's Repair Graft is manufactured from porcine small intestinal submucosa (SIS) and is nominally supplied in an oval configuration. The device is packaged in a lyophilized (dried) state, and is supplied sterile in a sealed double pouch system.

K063390 2/2

Substantial Equivalence:
The SURGISIS® Peyronie's Repair Graft is similar with respect to intended use, materials and technological characteristics to the above predicate devices in terms of section 510(k) substantial equivalence, as shown through bench and biocompatibility testing.

Discussion of Tests and Test Results:
The SURGISIS® Peyronie's Repair Graft met the requirements of extensive biocompatibility testing, viral inactivation testing, and mechanical testing, demonstrating suitability for use.

Conclusions Drawn from Tests:
Outcomes from the evaluation of the SURGISIS® Peyronie's Repair Graft provide evidence of its suitability for use in soft tissue repair and substantial equivalency to predicate devices in terms of intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2006

Cook Biotech Incorporated
% Mr. Perry W. Guinn
Vice President, Regulatory Affairs
& Quality Assurance
1425 Innovation Place
West Lafayette, IN 47906

Re: K062320
Trade/Device Name: Surgisis® Peyronie's Repair Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: August 8, 2006
Received: August 9, 2006

Dear Mr. Guinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062320

Indications for Use

510(k) Number (if known):

Device Name: **SURGISIS® Peyronie's Repair Graft**

Indications For Use:

The SURGISIS® Peyronie's Repair Graft is intended for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to the repair of tunica albuginea defects, and reinforcement in the repair of Peyronie's disease. The device is supplied sterile and is intended for one-time use.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restora...
and Neurological Devices

Page 1 of _____

510(k) Number K062320